

Applicants: Andrew Hoffman  
U.S.S.N. 09/616,483

### REMARKS

Applicant thanks the Examiner for the meeting of May 6, 2004, in which the only remaining issue of patentability (obviousness) was discussed.

Upon entry of the present amendment, claims 1, 3, 4, 6-45 are pending in the application. New claims 25-45 were added. Claim 25-35 are drawn to a device with holding chamber for holding the drug in a cloud suspension and a unidirectional inhalation valve located between the holding chamber and cup-shaped body/patient interface, which device not extend into the nose or mouth of a mammal and encloses only one nare of the mammal. The claims are supported by disclosure at page 1, lines 27-29; page 2, lines 10-12; page 9, lines 4-19, of the specification; and by Figs. 1, 2A-D, and 3A-E. New claims 25-35 are drawn to a method that requires the use of the device of claim 25 and requires that particles of the therapeutic composition to be administered to the animal are maintained in a cloud suspension at a size suitable for gaining access to small airways of the lung in the holding chamber of the device prior to inhalation by the animal. These claims are supported at page 2, line 24, to page 3, line 4; page 5, line 20, to page 6, line 5; and page 7, line 21, to page 8, line 10, of the specification; as well as by Figs. 1, 2A-D, and 3A-E.

No new matter has been added by this amendment.

### 35 U.S.C. § 103

The claims are subject to a rejection for obviousness over Barney et al. in view of a device with a spacer such as that described by Foley et al. This rejection is traversed.

Applicants respectfully submit that Barney et al. is not prior art under 35 U.S.C. §102(e), since the claimed invention was invented by Applicant prior to the effective date of the

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reference. Submitted with this response is a Declaration under 37 C.F.R. §1.131 executed by Andrew Hoffman, who is the sole inventor in the above-referenced patent application as well as a Declaration under 37 C.F.R. §1.131 executed by Ingrid A. Beattie, patent counsel to assignee of the above referenced patent application. The Declaration of Dr. Hoffman demonstrates his sole invention of the subject matter of the pending claims prior to the effective date of Barney et al., and the Declaration of Dr. Beattie further establishes diligence from a date prior to the effective filing date of Barney et al. to the date of constructive reduction to practice, i.e., the filing date of the above-referenced patent application. Thus, Barney et al. is not prior art. The secondary reference, Foley et al., fails to describe or suggest all of the limitations of the claimed invention. Therefore, this rejection should be withdrawn.

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### CONCLUSION

Applicants submit that the application is in condition for allowance and such action is respectfully requested.

No fees are believed to be due in connection with this amendment. The Commissioner is hereby authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 21629-001.

Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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